THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STATE OF OHIO,	)	
by Attorney General Betty D. Montgomery	)	
Antitrust Section	)	
140 East Town Street, 12th Floor	)	**CIVIL ACTION NO.**
Columbus, OH 43215	)	
	)	
and	)	
	)	
STATE OF MARYLAND,	)	
Office of the Attorney General	)	
Antitrust Division	)	
200 St. Paul Street	)	**JUDGE**
Baltimore, MD 21202	)	
	)	
and	)	
	)	
STATE OF FLORIDA,	)	
by Attorney General Robert A. Butterworth	)	
Antitrust Section	)	
PL-01, The Capitol	)	
Tallahassee, FL 32399-1050	)	
	)	
and	)	
	)	
STATE OF ALABAMA,	)	
by Attorney General Bill Pryor	)	
Consumer Affairs/Antitrust Section	)	
11 South Union Street	)	
Montgomery, AL 36130	)	
	)	
and	)	
	)	
STATE OF ALASKA,	)	**COMPLAINT**
by Attorney General Bruce M. Botelho	)	
1031 W. 4th Avenue, Suite 200	)	
Anchorage, AK 95501	)	
	)	
and	)	

STATE OF ARIZONA,)
by Attorney General Janet Napolitano)
1275 West Washington Street)
Phoenix, AZ 85007)
)
and)
)
STATE OF ARKANSAS,)
by Attorney General Mark Pryor)
Antitrust Division)
323 Center St. Ste. 200)
Little Rock, AR 72201)
)
and)
)
STATE OF CALIFORNIA,)
by Attorney General Bill Lockyer)
300 S. Spring Street, Suite 500 North Tower)
Los Angeles, CA 90013)
)
and)
)
STATE OF CONNECTICUT,)
by Attorney General Richard Blumenthal)
110 Sherman Street)
Hartford, CT 06105)
)
and)
)
STATE OF DELAWARE,)
by Attorney General M. Jane Brady)
Department of Justice, Antitrust Section)
820 N. French Street, 6th floor)
Wilmington, DE 19801)
)
and)
)
DISTRICT OF COLUMBIA,)
by Corporation Counsel Robert R. Rigsby)
Office of the Corporation Counsel)
441 4th Street, N.W.)
Washington, D.C. 20001)

and)
)
STATE OF IDAHO,)
by Attorney General Alan G. Lance)
Office of the Attorney General)
Len B. Jordan Building)
650 W. State St., Lower Level)
Boise, ID 83720-0010)
)
and)
)
STATE OF ILLINOIS,)
by Attorney General James E. Ryan)
100 West Randolph Street, 13th Floor)
Chicago, IL 60601)
)
and)
)
STATE OF KANSAS,)
by Attorney General Carla J. Stovall)
120 SW 10th Avenue, 2nd Floor)
Topeka, KS 66612-1597)
)
and)
)
COMMONWEALTH OF KENTUCKY,)
by Attorney General Albert B. Chandler III)
1024 Capitol Center Drive)
Frankfort, KY 40601)
)
and)
)
STATE OF LOUISIANA,)
by Attorney General Richard P. Ieyoub)
301 Main Street, Suite 1250)
Baton Rouge, LA 70801)
)
and)
)
COMMONWEALTH OF MASSACHUSETTS,)
by Attorney General Thomas F. Reilly)
One Ashburton Place)
Boston, MA 02108)

and)
)
STATE OF MICHIGAN,)
by Attorney General Jennifer M. Granholm)
Antitrust Section)
G. Mennen Williams Building, 6th Floor)
525 W. Ottawa Street)
Lansing, MI 48913)
)
and)
)
STATE OF NEW YORK,)
by Attorney General Eliot Spitzer)
Antitrust Bureau)
120 Broadway, Suite 26-01)
New York, NY 10271)
)
and)
)
STATE OF NORTH CAROLINA,)
by Attorney General Roy A. Cooper, III)
P.O. Box 629)
Raleigh, NC 27602)
)
and)
)
STATE OF OKLAHOMA,)
by Attorney General W.A. Drew Edmondson)
4545 N. Lincoln Boulevard, Suite 260)
Oklahoma City, OK 73105)
)
and)
)
STATE OF OREGON,)
by Attorney General Hardy Myers)
Department of Justice)
Justice Building)
1162 Court Street NE)
Salem, OR 97310)
)
and)

COMMONWEALTH OF PENNSYLVANIA,
by Attorney General D. Michael Fisher
Antitrust Section
14th Floor, Strawberry Square
Harrisburg, PA 17120

and

COMMONWEALTH OF PUERTO RICO,
by Secretary of Justice Anabelle Rodriguez
Department of Justice
PO Box 9020192
San Juan, PR 00902-0192

and

STATE OF RHODE ISLAND,
by Attorney General Sheldon Whitehouse
150 South Main Street
Providence, RI 02903

and

STATE OF SOUTH CAROLINA,
by Attorney General Charles M. Condon
Rembert C. Dennis Building
1000 Assembly Street, Suite 501
Columbia, SC 29211-1549

and

STATE OF TEXAS,
by Attorney General John Cornyn
P.O. Box 12548
Austin, TX 78711

and

STATE OF UTAH,
by Attorney General Mark L. Shurtleff
Antitrust Section
160 East 300 South
Salt Lake City, UT 84111

and

STATE OF VERMONT,
by Attorney General William H. Sorrell
Antitrust Unit
109 State Street
Montpelier, VT 05609-1001

and

TERRITORY OF THE UNITED STATES VIRGIN ISLANDS,
by Iver A. Stridiron, Attorney General
48B-50C Kronprindsens Gade
GERS Building, 2nd Floor
St. Thomas, U.S. VI 00802

and

STATE OF WASHINGTON,
by Attorney General Christine O. Gregoire
Antitrust Division
900 Fourth Avenue, Suite 2000
Seattle, WA 98164

and

STATE OF WISCONSIN,
by Attorney General James E. Doyle
17 West Main Street
Madison, WI 53702

Plaintiffs,

v.

BRISTOL-MYERS, SQUIBB CO.
345 Park Avenue,
New York, NY 10154

Defendant.

Plaintiffs, the States, Commonwealths, and Territories of Ohio, Maryland, Florida and Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Texas, Utah, Vermont, Virgin Islands, Washington, Wisconsin, and the District of Columbia (the "Plaintiff States" or "States"), by their Attorneys General, bring this action against defendant Bristol-Myers Squibb Co. ("Bristol") to secure damages, injunctive and other equitable relief for defendant's violations of federal and state antitrust laws, and allege as follows:

1. This case arises out of Bristol's unlawful maintenance of a monopoly over the United States market for paclitaxel based anticancer drugs and conspiracy to further its monopoly. In 1992 Bristol obtained approval from the U.S. Food and Drug Administration of its New Drug Application ("NDA") for Taxol®, the brand name for a medication for treating certain cancers, the active ingredient of which is the naturally occurring substance paclitaxel. FDA approval of the Taxol® NDA gave Bristol five years marketing exclusivity for the drug under the Hatch-Waxman Act, 21 U.S.C. § 355.

2. In an unlawful effort to extend the statutory five-year exclusivity period and wrongfully maintain its monopoly, Bristol fraudulently procured patents from the United States Patent and Trademark Office ("PTO"), improperly listed these invalid patents in the FDA's "Approved Therapeutic Equivalence Evaluations," ("the Orange Book"), and prosecuted numerous baseless lawsuits and regulatory procedures against the market entry of competitive, FDA approved generic bioequivalents to Taxol® ("generic Taxol®").

3. Bristol's scheme included a conspiracy with co-conspirator American Bioscience, Inc. ("ABI") to restrain competition from generic Taxol® through collusive litigation between Bristol and ABI that resulted in a contrived settlement under which Bristol, with knowledge of its invalidity, listed ABI's United States Patent No. 6,096,331 (the "'331 patent") in the Orange Book. This listing further precluded market entry by producers of generic Taxol®.

4. Bristol's misconduct interfered with and raised the costs of production and regulatory approval for generic Taxol® producers after December 29, 1997, caused the FDA to delay its review and approval, after December 29, 1997, of pending Abbreviated New Drug Applications ("ANDAs") for generic Taxol® bioequivalents. Bristol's unlawful scheme blocked Plaintiffs' access to a generic Taxol® bioequivalent until October, 2000, and further restricted the supply of generic Taxol® available to the product of a single competitor until April 2001.

5. As a result of Bristol's conduct, from December, 1997 to October 23, 2000, Plaintiffs and their citizens were required to purchase Taxol® and pay Medicaid and other reimbursements at monopoly prices. Bristol's unlawful conduct further caused Plaintiffs and their citizens to pay and reimburse higher than competitive prices for Taxol® and its generic bioequivalents after October 23, 2000. Absent Bristol's violation of the antitrust laws, patients would have been treated with generic Taxol® earlier in time, at a savings of millions of dollars to the Plaintiffs and their citizens.

JURISDICTION AND VENUE

6. Subject matter jurisdiction is proper pursuant Section 2 of the Sherman Act, 15 U.S.C. § 2 and Sections 4, 4C, 12 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 15c, 22 and 26

and under 28 U.S.C. §§ 1331, 1337. In addition to pleading violations of federal antitrust law, the States also allege violations of state antitrust, consumer protection and/or unfair competition statutes and related state laws, as set forth below, and seek damages, civil penalties and/or equitable relief under those state laws. All claims under federal and state law are based upon a common nucleus of operative facts, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction of the non-federal claims under 28 U.S.C. § 1367(a), as well as under the principles of supplemental jurisdiction. Supplemental jurisdiction will avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.

7. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 because: (i) Bristol transacts business, and is found within this district; and (ii) a substantial portion of the affected trade and commerce described below has been carried out in this judicial district.

PARTIES

8. Plaintiff States bring this action by and through their Attorneys General under statutory, equitable and/or common law authority: (a) in their proprietary capacities on behalf of their agencies, instrumentalities, colleges, universities and hospitals as direct and indirect purchasers of, and reimbursers for, paclitaxel based drugs, and as assignees of the antitrust causes of action of intermediate purchasers through which they procured such drugs; (b) in their sovereign capacities, as *parens patriae* under federal or state law; (c) in their sovereign and quasi-sovereign capacities as common law *parens patriae* on behalf of their respective states'

general economies; and (d) in their capacities as enforcers of state law to enjoin violations, to disgorge unjust profits, and to provide relief for injuries incurred in their states by securing damages and/or restitution, injunctions and other equitable remedies.

9. Defendant Bristol is a Delaware corporation with its principal place of business in New York, New York. Bristol is a leading U.S. pharmaceutical company and the manufacturer of several top-selling brand-name prescription drugs, including Taxol®. In 1999, Bristol's net sales worldwide were approximately $20 billion. In part Bristol carried out its sales of Taxol® through, and under the names of, its Mead Johnson division and its wholly owned and controlled subsidiary, Oncology Therapeutics Network. Throughout the period alleged, Bristol manufactured, marketed, distributed and sold substantial quantities of Taxol® in a continuous flow of interstate trade and commerce, and Bristol's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

CO-CONSPIRATOR

10. Co-conspirator ABI, not made a party hereto, is a California corporation with its principal place of business in Santa Monica, California. ABI conspired with Bristol and performed various acts as alleged hereinafter in furtherance of Bristol's scheme to monopolize and restrain trade.

BACKGROUND

Bristol Played No Role In the Discovery or Development Of Paclitaxel as an Anticancer Agent

11. Paclitaxel is the term designated by the U.S. Food and Drug Administration ("FDA") for an anticancer agent derived initially from the bark of the Pacific yew tree through a process that necessarily destroyed the tree. Paclitaxel is a naturally occurring compound. Its

anticancer properties were discovered and developed by researchers at the National Cancer Institute ("NCI"), a U.S. government research institute of the National Institutes of Health ("NIH"). Taxol® is a United States trademark registered in May 1992 to Bristol. Taxol® has been sold by Bristol since 1992 as a medication for treating certain cancers, and in particular ovarian and breast cancers.

12. Paclitaxel's antitumor qualities were discovered in the 1960s in studies performed and/or funded by the NCI. Bristol played no role in these studies. The NCI also performed extensive screening and toxicological studies on paclitaxel. Bristol played no role in these studies either. Without any involvement by Bristol, the federal government spent more than $32 million to develop economically feasible techniques to extract paclitaxel from yew tree bark and to create a clinically acceptable formulation for treating cancer-stricken humans.

13. NCI's clinical trials showed great promise for paclitaxel in treating refractory, *i.e.* unresponsive to previous treatment, ovarian cancers. The promising trials led the NCI to seek a commercial partner to submit and obtain FDA approval of a New Drug Application ("NDA") for a paclitaxel drug for indications of ovarian cancer, to develop and expand the sources of paclitaxel, and to manufacture and distribute the drug. At this point, 30 years after the discovery of paclitaxel, Bristol came into the picture.

The CRADA

14. The Federal Technology Transfer Act ("FTTA"), 15 U.S.C. § 3710, creates a procedure for the federal government to license its technology to a private party under a Cooperative Research and Development Agreement ("CRADA"). The CRADA sets forth in

writing the terms under which the private party is granted access to government research and technology.

15. In 1991, the NCI and Bristol entered into a CRADA for the development of a paclitaxel based drug to treat refractory ovarian cancer, and for the development of alternative sources of paclitaxel. In the CRADA, the NCI agreed to collaborate with Bristol on the design and implementation of clinical trials to permit Bristol to file an NDA with the FDA. Under the CRADA, the NCI gave Bristol exclusive use of existing and future data necessary for FDA approval of paclitaxel, sponsored clinical trials for Bristol's benefit, and granted Bristol exclusive access to the NCI's Investigative New Drug registration. In return, Bristol was required only to investigate and establish alternative natural and synthetic sources of paclitaxel, develop clinical and commercial supplies of paclitaxel, supply formulated paclitaxel for government sponsored clinical trials and compassionate distribution, assist in those trials for eighteen months, and prepare and file an NDA.

16. On July 22, 1992, Bristol filed an NDA seeking approval to market Taxol® for the treatment of ovarian cancer. The FDA approved Bristol's application on December 27, 1992, automatically triggering Bristol's five-year exclusive rights to market and sell Taxol® in the United States.

17. Bristol believed that its Taxol® exclusivity was limited to the five years granted under the Hatch-Waxman Act. In 1990, Bristol understood that paclitaxel was not patentable as either a composition of matter or as an antitumor agent in view of prior public use, public knowledge, and written publications regarding the drug.

18. In 1993 Bristol described its understanding of its Taxol® exclusivity to Congress:

> Taxol was never patented and no patent is even possible. The only exclusivity or protection afforded the company [Bristol] is the five years of protection from generic competition (Abbreviated New Drug Applications) granted under Hatch-Waxman to every new chemical entity.

Prepared Statement of Zola Horovitz, PhD., vice president, Business Development and Planning, Bristol-Myers Squibb Pharmaceutical Group, submitted January 25, 1993 to Hearing before the Subcommittee on Regulation, Business Opportunities and Technology of the Committee on Small Business, House of Representatives, attachment "Background: Taxol® and the CRADA Process," p. 4, (emphasis in original). Bristol further represented to Congress that:

> In addition, near-term generic competition for TAXOL is a certainty because TAXOL® is not a patented product. This absence of patent protection means that BMS only has protection against Abbreviated New Drug Application (ANDA) filings for five years from the date of approval as provided under the Hatch Waxman Act.

Id., attachment "Taxol® (paclitaxel): Key Considerations in Determining a Fair and Reasonable Price," p.6.

BRISTOL'S MONOPOLIZATION OF THE RELEVANT MARKET

Bristol's Invalid Taxol® Patents

19. On August 3, 1992, Drs. Renzo M. Canetta, Elizabeth Eisenhauer and Marcel Rozencweig filed patent application 07/923,628 (the "'628 application") in the United States Patent and Trademark Office ("PTO") as co-inventors for a variety of methods of administering paclitaxel as an antitumor drug. They assigned their patent rights to Bristol.

20. After the '628 application was rejected, on June 24, 1993, Bristol filed continuation application 08/109,331 (the "'331 application"), which it eventually abandoned. On

October 18, 1995, as a continuation of the '331 application, Bristol filed patent application 08/544,594 (the "'594 application"), which issued on June 24, 1997 as U.S. Patent No. 5,641,803 (the "'803 patent"). On September 19, 1996, as a continuation of the '594 application, Bristol filed application 08/715,914 (the "'914 application"), which issued on September 23, 1997 as U.S. Patent No. 5,670,537 (the "'537 patent").

21. Bristol obtained the '537 and '803 patents by: (a) knowingly and willfully making numerous material fraudulent omissions and misrepresentations to the PTO; (b) with clear intent to deceive the patent examiner; and (c) which material misrepresentations and omissions were the efficient, inducing and proximate cause of the issuance of the '803 and '537 patents.

22. Bristol fraudulently withheld from the PTO a document it distributed publicly at a meeting of the National Cancer Institute of Canada in April 1991 (the "*OV.9 abstract*"). The *OV.9 abstract* described a study to be undertaken which would administer Taxol® in doses of 135 mg/m^2 and 175 mg/m^2 over durations of three hours and twenty-four hours to premedicated patients. Bristol and Dr. Elizabeth Eisenhauer knew of the existence of the *OV.9 abstract* and of its dissemination. Further, Dr. Eisenhauer publicly discussed the *OV.9 abstract* at the April 1991 conference.

23. Bristol withheld the *OV.9 abstract* with the clear intent to deceive the PTO. Bristol and Dr. Eisenhauer appreciated the *OV.9 abstract* as a complete written description of their alleged inventions of the '803 and '537 patents. Due to its dissemination more than one year prior to Bristol's patent application, the *OV.9 abstract* constituted an anticipatory reference against all claims of the '803 and '537 patents. Thus, the *OV.9 abstract* was material because it

constituted a *prima facie* case of unpatentability that Bristol and its attorneys knowingly and intentionally failed to disclose to the PTO.

24. Bristol's withholding of the *OV.9 abstract* was an efficient, inducing and proximate cause for the issuance of the '803 and '537 patents. The *OV.9 abstract* would have been considered important and material by the patent examiner before whom the patents were prosecuted ("Examiner") under 37 C.F.R. 1.56(b) because it establishes, by itself or in combination with other references, a *prima facie* case of unpatentability as to the '803 and '537 patents. The *OV.9 abstract* constitutes "a printed publication [of the invention] in this or a foreign country . . . more than one year prior to the date of the application for [a] patent in the United States...", as provided in 35 U.S.C. 102(b). But for Bristol's fraudulent withholding of the material *OV.9 abstract*, the '803 and '537 patents would not have issued.

25. Bristol also fraudulently withheld a 59-page document detailing the protocol (the "*OV.9 protocol*") for the study described in the *OV.9 abstract*. The *OV.9 protocol* is dated no later than January 20, 1991. The principal authors of the *OV.9 protocol* were Drs. Canetta and Eisenhauer. The *OV.9 protocol* was distributed for approval to ethics review boards of institutions participating in the OV.9 study. The *OV.9 protocol* included data from studies of Taxol® that took place prior to the invention dates of the '537 and '803 patents, many of which were undisclosed to the PTO. Statements in the *OV.9 protocol* directly contradicted statements made by Bristol to the PTO during prosecution of the '803 and '537 patents, specifically:

> (a) "significant tumor shrinkage was observed in Phase I trials of Taxol® using 1 to 6 hour infusions." *OV.9 protocol* at 33.

(b) "Given prior results and the patient selection for the trial, an objective response rate of 35% can be expected." *OV.9 protocol* at 34.

(c) "There is no evidence to suggest that higher doses yield better rates of tumor regression, nor is there data to conclude that the more cumbersome 24-hour infusion (which is currently considered the "standard" recommended by NCI) is any safer than a shorter, more convenient infusion preceded by premedication." *OV.9 Protocol* at 13.

26. In this manner, Bristol and the named inventors informed the OV.9 participating institutions that they should expect the administration of paclitaxel in doses between 135-175 mg/m^2 over a 3-hour period to be successful because the prior art so indicated. Indeed, Dr. Eisenhauer testified in litigation on the '803 and '537 patents that statements in the *OV.9 protocol* regarding the efficacy of Taxol® were being provided as evidence to the participating institutions that Taxol® seemed to be effective, and that there was no reason not to expect short infusions to be effective.

27. The *OV.9 protocol* contradicts sworn statements by Dr. Canetta to the PTO in *Canetta Supp Decl*. at 2 and 6 that he was:

"thoroughly familiar with the literature in the art related to the use of Taxol® .... I have carefully studied the references...[t]hey all teach that short duration (i.e. < 6 hrs) Taxol® infusion protocols are ineffective in that they produce no observable tumor regression, and that they are unduly hazardous."

28. Bristol and the inventors withheld the *OV.9 protocol* and underlying studies with intent to deceive the PTO into issuing the '803 and '537 patents. Bristol and the inventors were not only aware of the detailed 59-page document, they authored it and discussed it with

institutions participating in their Taxol® study. Nonetheless, Bristol failed to disclose to the PTO their own statements in the *OV.9 protocol*, as well as several studies apparently underlying the premises of the *OV.9 protocol* that flatly contradict Bristol's statements to the PTO. The *OV.9 protocol* also contradicts arguments by Bristol, through their attorneys, to the Examiner that Dr. Canetta's declarations "establish that the art taught that Taxol® infusion durations of less than six hours were unduly toxic and produced no observable tumor regression." Bristol's failure to point out to the PTO its own inconsistent material statements regarding the teachings of prior art, the expected response rates, and the safety and efficacy of the administration of 135-175 mg/m^2 of Taxol® over 3-6 hours, evidences Bristol's intent to deceive the PTO into issuing the '803 and '537 patents.

29. Bristol's withholding of the *OV.9 protocol* and some of its underlying studies was an efficient, inducing and proximate cause for the issuance of the '803 and '537 patents. The *OV.9 protocol* and underlying studies would have precluded Bristol from arguing the alleged novelty and unexpected results of its alleged inventions, arguments that ultimately overcame the Examiner's rejections of the applications and led to the grant of the '803 and '537 patents. Had the Examiner been provided with the *OV.9 protocol* and underlying studies, Bristol could not have stated that its results were "entirely unexpected", nor could Bristol have represented to the PTO, as it did, that its discovery that administering Taxol® in doses of 135 mg/m^2 over three hours was safe and efficacious constituted a "truly astonishing" and "surprising discovery." October 18, 1995 Continuation Application at 11: 16 and 25, and 12: 5 and 18. The *OV.9 protocol* would have provided the Examiner with direct evidence, authored by the alleged inventors, that was contrary to Bristol's misrepresentations. Thus, but for Bristol's intentional

withholding of the material *OV.9 protocol* and underlying studies, the '803 and '537 patents would not have issued.

30. Bristol made further knowing, willful and fraudulent material misrepresentations to the PTO regarding a prior art reference which was before the PTO entitled *McGuire et al., Taxol: A Unique Antineoplastic Agent With Significant Activity In Advanced Ovarian Epithelial Neoplasms*, 111 Annals of Internal Medicine 273-279 (1989) ("*McGuire*"), while simultaneously fraudulently withholding from the PTO the following five material references:

(a) Bristol's Final Study of the McGuire Trial (June 1992);

(b) Rowinski et al., "Taxol: The First of the Taxanes, an Important New Class of Antitumor Agents," 19 Seminars in Oncology 646 (1992) (co-authored by Dr. Canetta) ("*Rowinski*");

(c) Eisenhauer et al., "European-Canadian Randomized Trial of Paclitaxel in Relapsed Ovarian Cancer," 12 Journal of Clinical Oncology 2654 (1992) ("*Eisenhauer*");

(d) Trimble et al., "Paclitaxel for Platinum-Refractory Ovarian Cancer," 11 Journal of Clinical Oncology 2405 (1993) (co-authored by Dr. Canetta), ("*Trimble*"); and

(e) Arbuck et al., "Clinical Development of Taxol," J. Nat'l Cancer Inst., Monographs No. 15 (1993), (co-authored by Dr. Canetta) ("*Arbuck*").

31. Nearly three years prior to Bristol's August 3, 1992 initial Taxol® patent application, *McGuire* taught efficacy in the treatment of ovarian cancer with paclitaxel. *McGuire* reported on a completed Phase II trial conducted with 47 drug-refractory ovarian cancer patients who were first premedicated to avoid hypersensitivity reactions and then administered the drug in doses from 110mg/m^2 to 250 mg/m^2 over 24 hours, every 22 days. *McGuire* noted a 30% response rate, either partial or complete, and because a complete

responder was administered only 110mg/m^2, concluded "[t]here appeared to be no correlation between the actual average dose of taxol and the likelihood for response." *McGuire* at 278.

32. Bristol and Dr. Canetta fraudulently misrepresented *McGuire*: (a) by arguing to the PTO that no prior art, including *McGuire*, taught that Taxol® was effective to treat ovarian cancer, stating: "[T]here is no teaching or suggestion that Ohnuma's, or anyone else's, method of administration of taxol would be effective in the treatment of ovarian cancer", August 16, 1993 Amendment and Response to 37 C.F.R. 1.111 and 1.115; and, (b) by stating to the PTO, "the outstanding rejection relies upon the unsupported premise that at the time the present invention was made, taxol was known to be clinically effective…[t]his is not true, and so the premise fails." Response Pursuant to 37 C.F.R. 1.116 in the 08/232,404 application ("'404 Application") dated March 23, 1995 at 2.

33. Bristol misrepresented to the PTO that, in contrast to *McGuire* and other researchers' work, its inventors demonstrated an effective method of administering Taxol® at low doses of 135 mg/m^2 over 24 hours. January 25, 1994 Response Pursuant to 37 C.F.R. 1.116 at 2. Simultaneously, Bristol repeatedly misrepresented to the PTO that *McGuire* predicted that doses over 250 mg/m^2 would be required to achieve efficacy. Bristol's repeated misrepresentations to the PTO regarding *McGuire* included the following:

> (a) *McGuire* "predicted that higher doses of taxol (250 mg/m^2) would yield better response rates...." January 25, 1994 Response Pursuant to 37 C.F.R. 1.116 at 4;
>
> (b) *McGuire* "expected that higher doses of taxol would be required for an effective therapeutic response." *Id.* at 5;
>
> (c) "In view of these reports [including *McGuire*], workers studying taxol's application had accepted that taxol doses much

higher than those initially recommended by Ohnuma et al. [135-170 mg/m^2] would be required." *Id*. at 6;

(d) *McGuire* "predicted that even higher doses of taxol (>250 mg/m^2) would be required to achieve the desired response." Preliminary Amendment in '404 Application filed May 25, 1994 at 4;

(e) "*McGuire* et al. surmised that higher doses of taxol (i.e., .250 mg/m^2) would be required." *Id.*

34. Bristol also knowingly misrepresented that it achieved higher objective response rates than were achieved in the prior art, asserting, for example, that:

> Applicants have shown an increase of 16% in the overall objective response rate; up from the prior art's 0%! Applicants' results are all the more surprising by the fact that all of the patients in the Applicants' study were considered drug refractory, and thus unlikely to respond to such therapy.

Response and Amendment under 37 C.F.R. § 1.111 in the 08/559,890 Application, dated May 21, 1996. In 1989 *McGuire* had reported a 30% response rate.

35. Bristol's foregoing misrepresentations of *McGuire* to the PTO were knowingly and willfully fraudulent. Prior to filing its patent applications for Taxol®, Bristol made the following representations to the FDA in connection with its New Drug Application for Taxol®:

(a) *McGuire* was the first to demonstrate the efficacy of Taxol®;

(b) *McGuire* was the first to demonstrate the efficacy of Taxol® in treating ovarian cancer;

(c) *McGuire* was the first to document that Taxol® was active after platinum failure, i.e., in refractory patients;

(d) *McGuire* had a response rate of 22%, which "clearly showed" that taxol was an "important new agent..."; and,

(e) *McGuire* demonstrated successful treatment at low doses of 135 mg/m^2 and 175 mg/m^2, and could be used for those patients who could not tolerate higher doses.

June 1992 "Final Study Report" on the McGuire trial, at 126-127.

36. To further misrepresent and conceal from the PTO the significance of *McGuire*, Bristol fraudulently withheld the *Rowinski, Eisenhauer, Trimble* and *Arbuck* references, each of which was co-authored by the alleged inventors. Like the June 1992 Final Study Report on the McGuire Trial, they contain praise and acknowledgment for the groundbreaking nature of the work represented in the 1989 *McGuire* reference. For example:

(a) In *Rowinski*, Dr. Canetta and his co-authors explain that McGuire taught both efficacy and safety (i.e., acceptable toxicity) of Taxol® at low dosages (from 110 mg/m^2 to 135 mg/m^2). *Rowinski* at 651.

(b) Dr. Eisenhauer "heralded" *McGuire* "as being of major significance, since responses were seen in both platinum-refractory and platinum-non-refractory patient groups. The finding of a new agent that was active for [refractory patients] was thought to be important..." and thus acknowledged that *McGuire* demonstrated the efficacy in both refractory and non-refractory patients. See *Eisenhauer* at 2655.

(c) In *Trimble*, Dr. Canetta and his co-authors again paid tribute to the 1989 McGuire reference as the first to demonstrate efficacy of Taxol® to treat refractory ovarian cancer in 1989. *Trimble* at 2405.

(d) In *Arbuck*, Dr. Canetta acknowledged and praised *McGuire* as being the first to show efficacy of paclitaxel and: [T]he first important indication of clinical activity in a Phase II trial ever reported in women with recurrent and refractory ovarian cancer. [Citation to *McGuire* omitted] *Arbuck* at 15.

37. Bristol fraudulently and materially misrepresented *McGuire*, and knowingly, willfully, fraudulently withheld the Final Study Report on *McGuire*, as well as *Rowinski,*

Eisenhauer, *Trimble* and *Arbuck*, with clear intent to deceive the Examiner into issuing the '803 and '537 patents. Bristol had a duty to point out and explain inconsistent statements in the fraudulently withheld references. Bristol could not have made the arguments and misrepresentations it did to the PTO about *McGuire* had the Final Study Report on *McGuire*, as well as *Rowinski, Eisenhauer, Trimble* and *Arbuck*, been disclosed. Bristol's misrepresentations and omissions are material within the meaning of 37 C.F.R. 1.56.

38 Bristol's fraudulent and material misrepresentations regarding *McGuire*, combined with its fraudulent withholding of the Final Study Report on *McGuire*, *Rowinski, Eisenhauer, Trimble* and *Arbuck*, were efficient, inducing and proximate causes of the issuance of the '803 and the '537 patents. But for Bristol's misrepresentations and omissions, the Examiner would have known that McGuire, not Bristol or Bristol's employees, discovered that administering low doses of Taxol® was safe and effective, and would not have allowed the patents to issue to Bristol.

39. During prosecution of the '803 and '537 patents and the applications from which they descended, Bristol deliberately withheld from the PTO a scientific abstract written by O'Connell et al., "Phase I Trial of Taxol Given as a Three Hour Infusion Every Three Weeks," published at 26 Proceedings of AACR, 169 (671) (1985) ("*O'Connell*"). *O'Connell* reported the results of the administration of three courses of Taxol® at each of the following dosages: 15, 30, 45, 75, 100, 135 and 160 mg/$m^{2.}$ The Taxol® was administered over a 2-3 hour infusion period every three weeks. *O'Connell* concluded and reported that paclitaxel "can be safely given as a 3 hour infusion every 3 weeks.…" *O'Connell* observed no hypotension and reported "no evidence of acute hypersensitivity reactions during the infusions". Prior to the dates of invention for the

‘803 and ‘537 patents, a person of ordinary skill in the art would have appreciated *O’Connell* as demonstrating a reduced hematologic effect compared with protocols for administering paclitaxel that included higher dosages and/or longer duration administration periods.

40. Bristol’s withholding of *O’Connell* from the PTO was knowingly and willfully fraudulent because *O’Connell* directly refutes, or is at least inconsistent with, Bristol’s assertions of patentability and its arguments opposing unpatentability that were relied on by the PTO. In particular, *O’Connell* refutes Bristol’s assertions to the PTO in the June 20, 1996 Supplemental Declaration of Renzo M. Canetta Pursuant to 37 C.F.R. 1.133 at 5 (“*Canetta Supp. Decl.*”), and the February 29, 1996 Declaration of Renzo M. Canetta Pursuant to 37 CFR 1.132 at 6 (“*Canetta Decl*.”), that available prior art taught that 3-hour infusions of paclitaxel in the claimed ranges of 135-175 mg/m^2 were “unsafe” and “would be unduly hazardous.” The O’Connell reference is therefore material within the definition of materiality in 37 C.F.R. 1.56(b), and Bristol knew it had a duty to disclose it. Further, because the PTO would have understood *O’Connell’s* administration protocol as teaching reduced hematologic effect compared to administration schedules requiring longer duration infusions, Bristol would not have been able to assert that its own claimed Taxol® treatment regimen “substantially reduces hematologic toxicity,” as it did in *Canetta Supp. Decl*. at 5.

41. Bristol withheld *O’Connell* with intent to deceive the PTO. Bristol could not have made the arguments for patentability (i.e., that prior to its alleged invention, paclitaxel was “unduly hazardous” at the claimed doses over a 3 hour infusion period, and that Bristol’s alleged invention substantially reduces hematologic toxicity), if it had disclosed *O’Connell*. Bristol had a duty to disclose and explain to the PTO prior art statements in *O’Connell* that were

contradictory to statements made by Bristol in support of its patent application. Bristol breached that duty.

42. Bristol's fraudulent withholding of *O'Connell* was an efficient, inducing and proximate cause of the issuance of the '537 and '803 patents. If provided to the Examiner, *O'Connell* would have directly refuted the characterizations of the prior art by Bristol's Dr. Renzo Canetta as being "unsafe" and "unduly hazardous," and as teaching away from the claimed invention in *Canetta Supp. Decl*. at 5 and in *Canetta Decl*. at 6. Disclosure of *O'Connell* would further have barred Bristol from arguing to the Examiner, as it did in its July 25, 1995 Response Pursuant to 37 C.F.R. 1.111 at 3, that its own discovery of the safe administration of Taxol® was "entirely unexpected in view of the prevailing teachings in the art at the time the invention was made". In addition, the Examiner would have appreciated the materiality and importance of *O'Connell*, in that it contains each and every element of the claims of the '803 patent, and all elements except the premedication element of the claims of the '537 patent. In consequence, the Examiner would have concluded that *O'Connell* anticipated the '803 patent, or least rendered obvious the claims of the '803 and '537 patents. Accordingly, but for Bristol's deceptive and material fraudulent withholding of *O'Connell*, the '803 and '537 patents would not have issued.

43. Bristol also knowingly and willfully made fraudulent misrepresentations to the PTO about *Kris et al., Phase I Trial Of Taxol Given As A 3-Hour Infusion Every 21 Days*, 70 Cancer Treatment Reports 605-607 (1986) ("*Kris*"). *Kris* reported on precisely the same courses reported in *O'Connell*, plus one additional course at 160 mg/m^2, three courses at 190 mg/m^2 and

one course at 230 mg/m^2. Bristol misrepresented to the PTO that *Kris* demonstrated that Taxol® was ineffective and unsafe, claiming:

> [o]ne of ordinary skill in the art would conclude, based upon the *Kris et al*. reference, that a 3-hour duration of infusion for the administration of paclitaxel would be unduly hazardous. Moreover, since *Kris et al*. observed no antitumor activity, virtually any toxicity manifestation would invalidate the treatment regimen used by *Kris et al*. Accordingly, one of ordinary skill in the art would conclude, consistent with the conclusions expressed by the authors themselves, that further investigation of the short duration infusion regimen of the *Kris et al.* regimen was not indicated.

Canetta Decl. at 6. Bristol failed to explain to the PTO that of the courses of Taxol administered in the Kris study, all administered at dosages of 160 mg/m^2 and below were safe in that they did not cause hypersensitivity reactions despite the lack of premedication. Bristol also failed to inform the PTO that of the only three courses that resulted in hypersensitivity reactions, the dosages were 190 mg/m^2 or 230 mg/m^2.

44. Years earlier, in its July, 1992 request for FDA approval of its New Drug Application for Taxol®, Bristol asserted to the FDA that *Kris* demonstrated that paclitaxel was safe. Specifically, Bristol asserted, "[d]oses of taxol up to 160 mg/m^2 over 3 hours were well tolerated with no severe toxicity…". June 1992 Final Study Report on *Kris* at 28. Bristol also asserted to the FDA that *Kris* taught that further investigation of Taxol® was warranted, and that the work of Kris and others, "led to the introduction of routine antihypersensitivity prophylaxis prior to taxol therapy." *Id.*

45. Bristol's fraudulent withholding of its Final Study Report on *Kris* from the PTO, its fraudulent statements to the PTO about *Kris*, and its intentional failure to submit and point out

its earlier inconsistent statements on the import of the Kris study demonstrate Bristol's clear intent to deceive the PTO into issuing the '803 and '537 patents.

46. Bristol's misrepresentations of *Kris* and its omission of its Final Study Report on *Kris* were an efficient, inducing and proximate cause leading to the issuance of the '803 and '537 patents. These misrepresentations and omissions were material in that, had Bristol disclosed to the Examiner the Final Study Report on *Kris*, the Examiner would have been aware of Bristol's appreciation and true interpretation of *Kris* as teaching the precise invention for which Bristol was seeking patent protection.

47. *Kris* has been held to invalidate by anticipation all claims in the '803 patent and all claims of the '537 patent, except claims 6 and 9, by the Federal Circuit Court of Appeals in *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc., et al.*, reported at 246 F.3d 1368 (2001).

48. With respect to the '537 patent, the district court in *Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp., et al*, 86 F. Supp.2d 433 (D.N.J. 2000), found that *Kris* "explicitly references all of the ['537] patent's limitations," *id*. at 441; that "one skilled in the art would have known exactly what *Kris's* premedication 'suggestion' entailed and would not have had to engage in further experimentation to gain possession of the patented ('537) invention," *id*.; and finally, that "Kris's direct suggestion to premedicate would enable one skilled in the art to follow the steps to create the patented method of administering Taxol®," *id*. at 442. The court concluded that claims 1, 2, 5, 6, 8 and 9 of the '537 patent were invalid as anticipated by *Kris*. The court had no occasion to rule on the remaining claims of the '537 patent because Bristol had not alleged that they were infringed. In a decision on April 20, 2001, the Federal Circuit

reviewed the district court's findings and affirmed them as to claims 1, 2, 5 and 8. The Federal Circuit remanded as to claims 6 and 9 for the district court to determine whether, "perhaps even as a matter of law," there were sufficiently few suitable premedicants that *Kris'* premedication suggestion would have been understood by one skilled in the art to suggest the particular premedicants described in these claims. 246 F.3d 1368 (Fed. Cir. 2001) at 1380.

49. Because the major difference between the '537 patent and the '803 patent is that the latter lacks the premedication step, the district court also found that the "claimed steps of the '803 patent (1-3 and 6) are explicitly present in *Kris*," and held those claims to be invalid as well. 86 F. Supp 2d at 443. Again, the Court did not rule on the other '803 patent claims because Bristol had not alleged their infringement. The Federal Circuit affirmed all the district court's findings as to the '803 patent.

50. Bristol also made fraudulent statements to the PTO regarding two additional publications, both relating to the same Phase I study: Longnecker et al., Phase I and Pharmacokinetic Study Of Taxol In Patients With Advanced Cancer, 4 Proceedings Of ASCO 32 (C-119) (1985) ("*The Longnecker Abstract"*), and Donehower et al., Phase I Trial of Taxol In Patients With Advanced Cancer, Cancer Treatment Reports Vol. 71, No. 12, at 1171, December 1987 ("*Donehower"*)**.**

51. *The Longnecker Abstract* is a preliminary report on the first 20 evaluable courses of Taxol® administered to the first 14 patients in the study. *The Longnecker Abstract* reports that Taxol was given over one hour every 21 days, starting at 15 mg/m^2 (7 courses), and escalating to 30 mg/m^2 (3 courses), 60 mg/m^2 (4 courses), 90 mg/m^2 (7 courses, 5 evaluable), and 135 mg/m^2 (1 course). *The Longnecker Abstract* did not report any hypersensitivity

reactions, but rather only "mild hematologic suppression," and stated that the study was "ongoing" with "[i]nvestigations at higher dosage levels continuing." *The Longnecker Abstract* does not mention or suggest the need for a longer infusion period, nor does it suggest that the study was unsuccessful, abandoned or a failure.

52. At the time *The Longnecker Abstract* was published in March of 1985, the Phase I study was still underway, as *The Longnecker Abstract* explicitly stated. It continued with 16 more patients who were given 51 more courses of Taxol® until August 23, 1985. As planned in the original study protocol, the investigators continued to escalate the Taxol® dosages from 135 mg/m^2 to 170 mg/m^2, 212 mg/m^2 and 265 mg/m^2, or until the maximal tolerated dose was achieved. The goals of the study were to: (1) determine the maximum tolerated dose which could be given intravenously every 21 days; (2) describe and quantitate the clinical toxic effects of taxol; and (3) seek preliminary evidence of therapeutic activity in patients with advanced cancer.

53. After the Phase I study was completed, *Donehower* reported the results of the entire study. Specifically, *Donehower* included data on the same 20 courses reported by *The Longnecker Abstract*, plus five more courses at 135 mg/m^2, nine courses at 170 mg/m^2, 30 courses at 212 mg/m^2 and five courses at 265 mg/m^2, for a total of 71 courses, 67 evaluable, administered over 1 or 6 hours every three weeks. *Donehower* reported five hypersensitivity reactions in the first 27 courses, including one near fatal reaction. Consequently, for the final 43 courses, a three drug premedication regimen was routinely used and the infusion duration was lengthened to six hours. With this adjustment, *Donehower* reported "only three minor reactions" in the final 43 courses. *Donehower* at 1176. Significantly, despite being a Phase I trial,

Donehower reported "evidence for antitumor effect in two patients[,]" one with lung cancer, and one with ovarian cancer. *Id*. *Donehower* did not mention or suggest that the infusion duration should be extended beyond six hours. Rather, *Donehower* concluded that its premedication regimen and six hour infusion duration made, "further clinical development of this drug more realistic and worthwhile based on the antitumor activity seen." *Id***.**

54. Bristol acknowledged and appreciated the antitumor activity discovered by *Donehower*, especially in the ovarian cancer patient. In its Taxol® NDA, based on Phase I trials, including the one which was the basis of *The Longnecker Abstract* and *Donehower*, Bristol told the FDA:

> (a) During the phase I clinical trials of taxol [including Kris and Donehower] an unusual level of antitumor activity was observed...," including in ovarian cancer and refractory patients. N.D.A. at 113.
>
> (b) "During the course of the phase I clinical studies of taxol (Ref. 164-172), hints of antitumor activity were observed in several patients with solid tumors and acute leukemias (Table 16 [which illustrates all phase I trials and their results]). *The main goal of these trials was the identification of the maximum tolerated dose (MTD) and not the accurate definition of response rates in a given tumor type. Still, it was encouraging that the drug could present signs of biological effectiveness, even if limited, in different tumor types*." *Id at 137*. (emphasis added).
>
> (c) "The observation of a decrease in the size of multiple peritoneal masses and the disappearance of gross ascites in a patient with epithelial ovarian cancer raised the interest of the investigators at the Johns Hopkins Cancer Center. This patient had a tumor which was refractory to platinum therapy; her clinical response lasted for 5 months and was accompanied by a marked improvement of her general condition. On this basis, the first phase II trial of taxol was planned by that institution." (referring to the ovarian cancer patient in the *Donehower* study). *Id*.

55. In its Final Study Report on *Donehower*, co-authored by Dr. Canetta, Bristol told the FDA that *Donehower* taught that Taxol was effective in two patients, that administering 170 mg/m^2 of Taxol over six hours with premedication would be safe even for heavily treated chemotherapy patients, that *Donehower* recommended doing so, and, most significantly, that an entire broad-based Phase II study was premised on the successful antitumor effect in the Donehower study, specifically reporting that:

> (a) In two patients there was evidence of antitumor activity....One patient with lung cancer...and another, a woman with ovarian cancer refractory to cisplatin therapy had a shrinkage of abdominal masses, disappearance ascites and improvement in her performance status for a 5 month duration. This was the only ovarian cancer patient in this phase I study, and her response led to a broader phase II study in ovarian cancer. Final Study Report on *Donehower* at 19.
>
> (b) Based on these data, the recommended doses for heavily and minimally treated patients would be 170 and 212 mg/m^2 respectively. Other toxicities were not a concern at these doses, i.e. the neurotoxicity was mild and apparently reversible and hypersensitivity reactions not significant when using premedication and avoiding rapid [i.e., 1 hour] i.v. infusion. *Id.* at 31.

56. Three years after receiving FDA approval for Taxol® based on these representations, Bristol and Dr. Canetta told the PTO exactly the opposite, that *Donehower* taught that administering Taxol® in six hours or less was ineffective and unduly hazardous, and that even the six hour treatment regimen should be abandoned, stating:

> (a) There is no teaching or suggestion that Ohnuma's, or anyone else's, method of administration of taxol would be effective in the treatment of ovarian cancer. Amendment and Response to 37 C.F.R. 1.111 and 1.115, August 16, 1993 at 8.
>
> (b) Donehower et al. fail to teach or suggest that paclitaxel has a clinically useful therapeutic index or possesses efficacious

> antitumor activity, even with this reportedly improved regimen of prolonged duration infusion. *Canetta Decl.* at Paragraph 19.
>
> (c) Taken together, Donehower et al. and Kris et al. fail to teach or suggest that paclitaxel is an efficacious antitumor agent. Kris et al. reported that no antitumor activity was observed, and that HSRs were treatment limiting for paclitaxel administered at doses of 15-230 mg/m^2/3hrs**.**" *Id*. at Paragraph 20. (emphasis added)
>
> (d) [T]he prior art taken as a whole, particularly Donehower et al. and Kris et al. taken together with Wiernik et al., unambiguously teach that 1 - 6 hr. duration infusion schedules did not warrant further investigation or usage; and suggest that even the > 6 hour infusion schedule should be abandoned in favor of a 24 hour infusion schedule. Notwithstanding, Applicants have investigated a short duration infusion regimen; and have shown that the regimen is both efficacious and particularly advantageous in reducing hematologic toxicity. *Id* at Paragraph 23.

57. After receiving Canetta's Declaration, the Examiner rejected Bristol's application over *The Longnecker Abstract*, stating that:

> Longnecker teaches a one hour infusion with mild hematologist [sic. hematologic] suppression. In view of this, one of ordinary skill would be motivated to employ Taxol for three hours to get reduced hematologic response, in the absence of a side-by-side comparison. Canetta's declaration does not discuss Longnecker.

Office Action 10/18/95.

58. Neither Bristol nor Dr. Canetta had discussed *The Longnecker Abstract* prior to the Examiner's October 18, 1995 rejection because Bristol failed to submit it to the PTO. In response to this rejection, Bristol and Dr. Canetta, submitted several responses and declarations asserting repeatedly that *The Longnecker Abstract* was a "failed[,]" "abandoned[,]" and "unsuccessful" experiment, rather than a report on the beginning stage of a successful trial. *See* responses Pursuant to 37 CFR 1.111 of June 3, 1996, June 24, 1996, and Supplemental

Declaration of Renzo M. Canetta Pursuant to 37 CFR 1.132, dated June 20, 1996. Further, Dr. Canetta stated that:

> The Longnecker reference contributes nothing relevant to the art that is not taught by Kris et al. or Donehower et al. and addressed in my earlier Declaration. Indeed, Longnecker is consistent with those references in that they all teach that short duration (i.e., < 6 hrs) Taxol infusion protocols are ineffective in that they produce no observable tumor regression, and that they are unduly hazardous.

Supp. Canetta Decl. at Paragraph 15. Neither Dr. Canetta nor Bristol addressed the Examiner's concern about *The Longernecker Abstract's* reference to "mild hematologic suppression." Instead, they portrayed the *Longnecker Abstract* as abandoned, even at low doses, because it was purportedly "unduly hazardous."

59. Bristol fraudulently concealed from the PTO that the "mild hematologic suppression" relative to other administration schedules reported in *The Longnecker Abstract* was precisely the "reduced hematologic toxicity" Bristol claimed in the '803 and '537 patents, which it had described to the PTO as "unexpected." Bristol fraudulently withheld from the PTO its Final Study Report on *Donehower* to the FDA, in which Dr. Canetta and his co-authors explained that *Donehower* demonstrated efficacy even in ovarian cancer, and recommended the safe and efficacious administration of Taxol at 170 mg/m^2 and 212 mg/m^2 with premedication over six hours.

60. Bristol's and Dr. Canetta's fraudulent statements to the PTO about *The Longnecker Abstract* and *Donehower,* and withholding from the PTO its Final Study Report on *Donehower*, co-authored by Dr. Canetta, which contained inconsistent, and thus material, statements on the import of both publications, demonstrate Bristol's clear intent to deceive the PTO into issuing the '803 and '537 patents.

61. Bristol's misrepresentations of *The Longnecker Abstract* and *Donehower* and its omission of its Final Study Report on *Donehower* were an efficient, inducing and proximate cause leading to issuance of the '803 and '537 patents.

62. Bristol and inventors Canetta, Eisenhauer and Rozencweig also fraudulently withheld their best mode of practicing the '803 and the '537 patents from the PTO. Prior to filing the '628 application on August 3, 1992, the inventors understood that there was a method of practicing their invention better than any other method, and they deliberately withheld it from the '628 application, and during the entire prosecution of the '803 and '537 patents.

63. At the time of filing the '628 application, the inventors and Bristol understood that the best method of administering paclitaxel parenterally was to dissolve it in "cleaned," i.e., purified, polyoxyethylated ("POE") Castor Oil and dehydrated alcohol. To produce what it sometimes referred to as "BMS purified POE Castor Oil," Bristol purchased a POE Castor Oil product sold by BASF under the trademark "Cremophor® EL," and used a proprietary process to further "clean" or "purify" it before using it in solution with paclitaxel to manufacture Taxol®.

64. As early as 1990, Bristol's Taxol Team, of which Dr. Canetta was a member, recognized the importance of the source and composition of the cremophor used in formulating Taxol®, and worked with the NCI to discover or develop the specific cremophor formulation that was safe and effective for use in the manufacture of Taxol®.

65. On July 21, 1992, thirteen days prior to filing the '628 application at the PTO, Bristol informed the FDA that its commercial method of manufacturing Taxol® begins with "Cremophor® EL (cleaned)," and that the final composition of each 5 milliliter vial of Taxol® contained 527 milligrams of "Polyoxyethylated castor oil (cleaned)." Bristol further assured the

FDA that "[T]he drug product composition used in the clinical studies is identical to that disclosed in this NDA submission." Each of these clinical studies was the subject of an in-depth Final Study Report co-authored by Dr. Canetta and submitted to the FDA.

66. Later in 1992, in response to Bristol's representations about its method of manufacturing Taxol®, the composition of Taxol®, and the formulation of Taxol® used in the clinical trials, the FDA specifically acknowledged the role of BMS-purified Cremophor® EL as a solvent in the formulation of Taxol®.

67. In contrast to Bristol's emphasis to the FDA on its proprietary "purified" Cremophor® EL, and its deliberate and consistent decision to use only BMS-purified Cremophor® EL in its clinical trials, Bristol and the inventors fraudulently concealed from the PTO their belief that "purified" or "cleaned" Cremophor® EL was the best mode of practicing either the '803 or the '537 patents. Instead, it disclosed only that:

> Each 5 ml vial contained 6 mg/ml taxol in polyethoxylated[sic] castor oil (Cremophor EL) 50% in dehydrated alcohol, USP 50%. While an emulsion of taxol in polyethoxylated[sic] caster oil in dehydrated alcohol is utilized as a vehicle in a preferred embodiment, it is contemplated that other pharmaceutically acceptable vehicles for taxol may be used.

The '803 patent at Col. 6:57-63; and the '537 patent at Col. 6:61-67. Bristol withheld its preference for purified POE from the PTO.

68. Information about BMS-purified POE Castor Oil and about Bristol's proprietary process to produce it would have material to the PTO because it affects patentability. In prosecuting the '628 application with the PTO, Bristol, Canetta, Eisenhauer and Rozencweig, like all inventors, were under an absolute duty to have disclosed their best mode at the time the

patent application was filed. When Bristol and the inventors failed to disclose the best mode of which they were aware at the time of filing the application, the resulting '537 and '803 patents, were rendered invalid. 35 USC § 112.

69. Bristol's and the inventors' clear intent to deceive the Examiner into issuing the '803 and '537 patents without disclosure of their best mode can be inferred by contrasting the language used in the '628 application with Bristol's Taxol® NDA, filed 13 days earlier. The '628 application omits all language about "purified" Cremaphor® EL and about Bristol's proprietary purification process, while Bristol's NDA is replete with references to "clean" Cremaphor® EL. Bristol intended to keep its purified Cremophor® EL, and its process for producing it, a secret from the PTO and the public.

70. The Examiner would not have issued the '803 or the '537 patent had he known that Bristol and the inventors fraudulently withheld their best modes of practicing those inventions.

Bristol's Use of Baseless, Sham Litigation and Predatory Regulatory Procedures and Exclusive Licensing to Exclude Competition and Maintain its Monopoly

71. Upon obtaining the '537 and '803 patents, Bristol promptly listed them in an FDA publication, *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The FDA requires each NDA holder to list in the Orange Book each patent for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the [NDA holder's] drug." 21 U.S.C. §§ 355(b)(1) and (c)(2). Bristol's listing of the '537 and '803 patents in the Orange Book was knowingly baseless because Bristol knew that these patents were invalid, had been procured by inequitable conduct and fraud, and could not form a reasonable basis for patent

infringement action against a person not licensed by Bristol engaged in the manufacture, use or sale of Taxol® or its generic bioequivalent.

72. Pursuant to Section 5050(2)(B) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), a pharmaceutical company seeking approval of an Abbreviated New Drug Application ("ANDA") for a generic version of an FDA-approved drug must provide the company holding the approved NDA with notice of a certification in the ANDA that the manufacture, use and sale of the generic drug will not infringe patents listed in the Orange Book.

73. Beginning on July 30, 1997, various pharmaceutical companies filed ANDAs with the FDA for generic paclitaxel products and provided Bristol with notice of certifications under Section 505(j) of the Hatch-Waxman Act as to Bristol's Taxol® patents. The certifications claimed that the '803 and '537 patents were invalid and that U.S. Patent No. 5,496,804 (the "'804 patent"), a government patent licensed exclusively to Bristol, did not claim any of the proposed indications for which the generic companies sought approval.

74. In response to each of these notices, Bristol brought actions against Boehringer Ingelheim Corp., Ben Venue Laboratories, Inc. ("Ben Venue"), Bedford Laboratories, Immunex Corporation, Pharmachemie B.V., Zenith Goldline Pharmaceuticals, Inc. ("Zenith"), IVAX, Pharmaceuticals, Inc. ("IVAX"), Mylan Pharmaceuticals, Inc., Marsam Pharmaceuticals, Inc. and Schein Pharmaceuticals, Inc., in the United States District Court for the District of New Jersey alleging infringement of the '803, '537 and '804 patents.

75. Simply by filing these patent infringement actions within 45 days of receiving the notice of Section 505(j) certification, Bristol automatically obtained an additional market exclusivity by staying FDA approval of the relevant ANDAs for the lesser of 30 months or a final non-appealable determination regarding the invalidity of the patent. Had Bristol not obtained this additional market exclusivity, these generic competitors intended and were prepared to enter the market upon receipt of FDA approval.

76. To gain this additional exclusivity, Bristol asserted patent infringement allegations based on patents it knew or should have known were invalid or that did not claim any of the proposed indications. Bristol's patent infringement claims were brought in bad faith and were objectively baseless.

77. Ben Venue, IVAX and IVAX subsidiaries, Zenith, and Baker Norton Pharmaceuticals, Inc. ("BNP"), asserted counterclaims against Bristol based on allegations similar to those asserted in this complaint. These companies moved for summary judgment on certain aspects of their counterclaims. As alleged above, on March 2, 2000, the district court ruled that all claims asserted in the '537 and '803 patents (other than those directed specifically to the treatment of ovarian cancer) were invalid on the ground of anticipation.

78. On April 5, 2000, the New Jersey court signed a stipulation and order in which, *inter alia*, Bristol agreed to permanently disclaim two claims (claims 4 and 5) of the '803 patent and four claims (3, 4, 7 and 10) of the '537 patent that had not been invalidated, so that a final judgment could be entered under Federal Rule of Civil Procedure 54(b) on the issue of patent validity. In the stipulation, Ben Venue agreed to delete from its pending ANDA any recommendations to administer paclitaxel with granulocyte-colony stimulating factor (the subject of the '804 patent), and Bristol agreed not to sue Ben Venue or its customers on a claim of infringing the '804 patent. The court entered judgment in accordance with the stipulation and order on June 30, 2000.

79. On August 31, 2000 as part of its ongoing effort to delay generic market entry, Bristol filed another lawsuit against BNP in a Florida State Court, seeking discovery to determine the precise composition of BNP's paclitaxel product. The pretext for this new lawsuit was Bristol's assertion that it needed to determine whether IVAX and BNP were infringing Bristol's patent No. 5,504,102 (the '102 patent) and whether BNP's generic paclitaxel product had the same inactive ingredients as Taxol®. The suit was objectively baseless and was brought

for the purpose and with the effect of restraining the entry of IVAX and BNP as competitors in the market for paclitaxel based drugs.

80. On September 12, 2000, Bristol filed yet another lawsuit in the United States District Court for the Southern District of New York ostensibly asking, by way of a declaratory judgment action, for an interpretation of its obligations to list a patent for certain dosage forms of Taxol® which had been issued to ABI – the '331 patent. The suit named ABI, IVAX, and BNP as defendants. On September 15, 2000, BNP received final FDA approval of its ANDA, and on October 18, 2000 Bristol voluntarily dismissed the case. Because a California Court had previously ruled that ABI could not sue Bristol under any colorable legal theory for failing to have the '331 patent listed in the Orange Book, this lawsuit was objectively baseless from its inception.

81. Such objections and misrepresentations included claims that ANDA applicants must demonstrate that the POE Castor Oil used as a solubilizing agent in their formulations was identical to the POE Castor Oil Bristol advertised as "further purified by a BMS proprietary process", or undergo new safety and efficacy trials.

82. Bristol further sought to and did delay and restrain entry of generic Taxol® to the market and raise the costs of generic Taxol development and production by acquiring in 1990, and maintaining thereafter, exclusive licenses on patented processes for the semi-synthetic production of paclitaxel for the purpose of excluding generic competitors to Taxol®.

83. Absent Bristol's unlawful conduct, the FDA would, on information and belief, have approved a generic Taxol® product and that product would have been produced and marketed in the United States at least as early as January 1,1999.

Bristol's Collusion With ABI To Perpetuate Its Monopoly

84. Commencing at least as early as August 2000, Bristol engaged in a combination and conspiracy with ABI, the purpose and effect of which was to maintain Bristol's monopoly in the market for paclitaxel based drugs and further foreclose market entry by generic Taxol® by means of the baseless assertion of invalid claims related to ABI's '331 patent.

85. On August 1, 2000, the PTO issued U.S. Patent No. 6,096,331 (the "'331 patent") to ABI. The '331 patent claims certain dosage forms of Taxol®. Both ABI and Bristol knew that any infringement claim under the '331 patent would be baseless and invalid if based upon the dosage forms long utilized by Bristol under its 1992 NDA, or by a generic producer under an ANDA for a generic Taxol®, because Bristol's own practice and labeling of the drug, along with numerous printed publications, had anticipated those patent claims.

86. Before August 11, 2000, Bristol knew that the '331 patent was invalid and that any claims that Taxol® or generic Taxol® infringed the '331 patent would be baseless. Bristol was also aware that its listing of the '331 patent in the Orange Book would confront any manufacturer submitting an ANDA for generic Taxol® with further procedural delay and costs as well as the prospect of an infringement action. Such a dispute would result in a stay of up to thirty months in the FDA's approval process, an unwarranted extension of Bristol's monopoly.

87. On August 11, 2000, ABI filed suit against Bristol in the U.S. District Court for the Central District of California. On the same day, Bristol and ABI collusively stipulated to entry of a temporary restraining order under which Bristol agreed to list the '331 patent in the FDA Orange Book. Bristol and ABI agreed to this order with knowledge that there was no legal basis for the order or for the underlying suit. Based upon Bristol and ABI's misleading activity

in the form of a pretense of a justiciable controversy, the Court entered the requested temporary restraining order. In truth, there was no legal controversy. Bristol and ABI were simply collaborating in order to obtain a court order which would require Bristol to list the '331 patent in the Orange Book.

88. Within hours after the parties' sham court action, Bristol filed the '331 patent for listing in the Orange Book knowing that it had no reasonable basis for doing so.

89. On August 28, 2000, the FDA sent a letter to IVAX tentatively approving its pending ANDA for generic Taxol®. In this letter and in reliance on Bristol's baseless listing of the '331 patent in the Orange Book, the FDA explicitly withheld final approval and informed IVAX that it could not receive final approval "…until all legal and regulatory issues surrounding [IVAX's] challenge of the '331 patent have been satisfactorily resolved."

90. But for Bristol's conspiracy and agreement with ABI to secure an unwarranted listing of the '331 patent in the Orange Book through baseless and collusive litigation, IVAX would have received final FDA approval to manufacture and market generic Taxol® in competition with Bristol on or before August 28, 2000.

91. On September 7, 2000, the Central District of California dismissed ABI's lawsuit against Bristol, holding that there was no private right of action to enforce the provisions of the FFDCA. The Court ordered that Bristol "shall use its best efforts to cause the delisting of [the] '331 patent from the Orange Book" and further that "ABI shall cooperate with [Bristol] in its efforts to delist the '331 patent pursuant to the [agreed temporary restraining order]."

92. In furtherance of its conspiracy with Bristol, on September 7, 2000, ABI filed a baseless patent infringement suit in the U. S. District Court for the Central District of California

against Baker Norton Pharmaceuticals Inc., Zenith Goldline Pharmaceuticals, Inc. and IVAX Corporation, all of which had pending ANDAs to produce and market generic Taxol® in competition with Bristol. The next day, Bristol informed the FDA of the lawsuit, claiming that the litigation barred the FDA from approving those pending ANDAs for thirty more months.

93. On September 11, 2000, Bristol again submitted the '331 patent to the FDA for Orange Book listing. Three days later, on September 14, 2000, Bristol sent a letter to the FDA to undo its original listing of the '331 patent only "to the extent it was compelled by the [temporary restraining order]." Bristol maintained to the FDA that its actions should not be construed as withdrawing its second listing of the '331 patent.

94. On September 15, 2000, the FDA determined that Bristol's September 11th Orange Book listing was untimely because it was received more than 30 days after the '331 patent was issued, *see* 21 U.S.C. § 355(c)(2). On this same day, the FDA granted BNP final approval to market its paclitaxel product. BNP's final FDA approval was subsequently vacated on November 6, 2001, when the United States Court of Appeals for the District of Columbia Circuit ruled that the FDA had acted contrary to the Administrative Procedure Act in connection with the Orange Book listing of the '331 patent.

95. Meanwhile, on September 20, 2000, IVAX began promotion of its paclitaxel product and announced that it would begin shipping the product in no more than three weeks. However, because ABI's California litigation had caused IVAX's contract drug manufacturer to shift its production focus to another medicine, IVAX was not able to begin shipping its product until October 23, 2000, and the shipments were in smaller quantities than they would have been in the absence of Bristol's listing of the '331 patent in the Orange Book.

96. IVAX's commercial marketing of generic Taxol® began on October 23, 2000. For 180 days thereafter, Ivax was the only generic manufacturer permitted to market generic paclitaxel because of the exclusivity incentives contained in the Hatch-Waxman Act. This delayed market entry and limitation to only one competitor for a period of 180 days was caused by Bristol's knowing, fraudulent, and willful procurement of the '803 and '537 patents, its acts in causing these patents (with knowledge they were procured by fraud) to be listed in the Orange Book, its collusion with ABI, and its initiation and prosecution of sham infringement litigation related to these patents, and its baseless and sham listing of ABI's '331 patent in the Orange Book.

97. On January 11, 2002 the U.S. District for the Central District of California ruled that all claims of the '331 patent asserted against the ANDA applicants for generic Taxol® were invalid.

98. Bristol did not withdraw its baseless listing of the '331 patent until January 17, 2002.

Relevant Market

99. One relevant product market is the United States market for paclitaxel based drugs. Sellers that desire to manufacture, market, or sell paclitaxel based drugs in the United States must receive FDA approval. Such approval limits the treatment indications that may appear on the label and labeling for which the drug may be advertised or promoted. Without regard to the FDA's limitations on labeling and marketing, however, once a paclitaxel based drug is approved, those making the decisions whether to purchase and/or utilize such drugs or how to fill a prescription for a paclitaxel based drug are free to substitute one therapeutically

equivalent paclitaxel based drug for another. Taxol® and generic Taxol® are substitutes in the eyes of such decision-makers and belong in the same relevant product market. For those situations where paclitaxel based drugs are purchased or prescribed, there is no reasonable substitute for paclitaxel based drugs in the eyes of those making the decision to purchase and/or use paclitaxel based drugs.

100. The relevant geographic antitrust market is the United States (50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Territory of the United States Virgin Islands and other United States commonwealths, territories and protectorates). To manufacture, sell, or market paclitaxel based drugs in the United States, one must receive approval from the FDA.

101. Until October 23, 2000, Bristol was the sole manufacturer selling paclitaxel based drugs in the United States. For the period October 23, 2000 to April, 2001 Bristol was one of two manufacturers selling paclitaxel based drugs in the United States.

COUNT I

Monopolization in Violation of Section 2 of the Sherman Act

102. Plaintiffs incorporate by reference the preceding allegations.

103. Bristol has monopoly power in the market for paclitaxel based drugs in the United States. Pursuant to the Hatch-Waxman Act, Bristol was given a lawful monopoly over sales of Taxol® from December 1992 to December 1997. Through various unlawful means, including those alleged above, Bristol sought to and did unlawfully extend and maintain its monopoly from December 1997 until at least April 2001.

104. Bristol has maintained its monopoly power in the relevant market since its five-year period of marketing exclusivity expired, in violation of Section 2 of the Sherman Act, 15

U.S.C. § 2, through willful, anticompetitive, exclusionary conduct as described above and not through superior skill, foresight, industry or an historical accident, or through legitimate competitive activities. As alleged above, Bristol has secured patents through inequitable conduct and fraud on the PTO, has caused these patents to be listed in the Orange Book without any objective basis for doing so and with knowledge of their invalidity, has initiated and prosecuted a pattern of sham and baseless regulatory procedures and infringement and other litigation based upon patents it knew to be invalid and procured by fraud, has secured exclusive patent licenses to processes for the semi-synthetic production of the essential active ingredient paclitaxel, foreclosing its competitors use of that technology, has caused the listing of the '331 patent in the Orange Book with knowledge that it could not form the basis for a good faith infringement action and colluded with ABI to create the pretext that such a basis for alleging infringement could exist, all for the purpose and with the effect of interfering with and delaying the availability of generic paclitaxel based drugs in the United States and of excluding and restraining competition in the market for such drugs.

105. Bristol's anticompetitive conduct alleged herein has injured competition in the relevant market by maintaining Bristol's power to exclude competitors, reduce output, charge monopoly prices, reap monopoly profits and otherwise thwart competition in the relevant market.

106. Bristol's conduct in unlawfully maintaining its monopoly in the paclitaxel market has injured Plaintiffs in their business and property. Through its wrongful conduct, Bristol was able to maintain monopoly prices on its Taxol® products and deprive the Plaintiffs of access to lower-priced generic paclitaxel products during a period commencing at least as early as January 1, 1999.

COUNT II

Conspiracy in Violation of Section 2 of the Sherman Act

107. Plaintiff States incorporate by reference the preceding allegations.

108. Beginning no later than August 2000 and continuing at least through October 2000, Bristol and ABI engaged in a continuing contract, combination and conspiracy to monopolize sales, restrict output and exclude generic competition in the United States market for the manufacture and sale of paclitaxel based drugs in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

109. In furtherance of this contract, combination and conspiracy, Bristol and ABI did those things that they conspired and combined to do, including:

(a) ABI filed a baseless lawsuit against Bristol in federal court alleging that Bristol improperly failed to list the '331 patent in the Orange Book;

(b) Bristol and ABI jointly sought a temporary restraining order compelling Bristol to list the '331 patent in the Orange Book;

(c) Bristol and ABI collaborated in preparing the complaint and briefs necessary to commence the lawsuit and obtain the temporary restraining order;

(d) Bristol and ABI "settled" their fabricated "dispute" and asked the court to sign a proposed Final Order and Judgment which would have required Bristol to maintain the '331 patent listing in the Orange Book and made a specific factual finding that the '331 patent was properly listed; and

(e) Bristol agreed to compensate ABI for its participation in the conspiracy.

110. As a result, in part, of the unlawful conspiracy between Bristol and ABI, Bristol was able to maintain and extend its monopoly power in the U.S. market for paclitaxel based anticancer drugs during and after August 2000.

111. The contract, combination and conspiracy between Bristol and ABI has injured Plaintiffs in their business and property beginning at least as early as August 2000, by restraining and delaying the entry into the market of producers of generic Taxol®, thereby depriving Plaintiffs of the opportunity to purchase paclitaxel based anticancer drugs in a competitive market and restraining Plaintiffs' access to lower-priced generic paclitaxel based products. As a result Plaintiffs have purchased millions of dollars worth of paclitaxel based drugs at artificially high, anticompetitive prices.

SUPPLEMENTAL STATE LAW CLAIMS

112. Plaintiff State of Alabama repeats and realleges each and every allegation contained in paragraphs 1 through 111.

113. Defendant's acts violate, and Plaintiff State of Alabama is entitled to relief under the Deceptive Trade Practices Act, Section 8-18-1, *et seq*,. Code of Alabama 1975. Section 8-19-11, Code of Alabama 1975 provides for civil penalties and reasonable attorney fees.

114. Plaintiff State of Alaska repeats and realleges each and every allegation contained in paragraphs 1 through 111.

115. Defendant's acts violate, and plaintiff State of Alaska is entitled to relief under, AS 45.50.471(a), AS 45.50.495, AS 45.50.501, AS 45.50.551, and AS 45.50.562-.596.

116. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 111.

117. Defendant's acts violate, and plaintiff State of Arizona is entitled to relief under, Arizona's Uniform State Antitrust Act, A.R.S. §§ 44-1401 *et seq.*

118. Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 111.

119. Defendant's acts violate, and plaintiff State of Arkansas is entitled to relief under, the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*

120. Plaintiff State of California repeats and realleges each and every allegation contained in paragraphs 1 through 111.

121. Defendant's acts violate, and plaintiff State of California is entitled to relief under, The Cartwright Act, California Business & Professions Code sections 16700 *et seq.*, and the Unfair Practices Act, California Business & Professions Code sections 17000 *et seq*.

122 Plaintiff State of Connecticut repeats and realleges each and every allegation contained in paragraphs 1 through 111.

123. Defendant's acts violate, and plaintiff State of Connecticut is entitled to relief under, the Connecticut Antitrust Act, Conn. Gen. Stat.§ 35-24 *et seq*., and the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a *et seq.*

124. Plaintiff State of Delaware repeats and realleges each and every allegation contained in paragraphs 1 through 111.

125. Defendant's acts violate, and plaintiff State of Delaware is entitled to relief under, Delaware Antitrust Act, 6 Delaware Code § 2101 *et seq.*, the Freedom of Information Act, 29

Delaware Code § 10001 *et seq.*, and the Delaware Deceptive Trade Practices Act, 6 Delaware Code § 2501 *et seq*.

126. Plaintiff District of Columbia repeats and realleges each and every allegation contained in paragraphs 1 through 111.

127. Defendant's acts violate, and plaintiff District of Columbia is entitled to relief under, the District of Columbia Antitrust Act, D.C. Code, 2001 Ed. § 28-4501 *et seq.*, including, without limitation, D.C. Code, 2001 Ed. § 28-4507, pursuant to which plaintiff District of Columbia seeks threefold the damages sustained by natural persons.

128. Plaintiff State of Florida repeats and realleges each and every allegation contained in paragraphs 1 through 111.

129. Defendant's acts violate, and plaintiff State of Florida is entitled to relief under, the Florida Antitrust Act of 1980, 542.15 Florida Statutes, *et seq*., and the Florida Deceptive and Unfair Trade Practices Act, 501.201 Florida Statutes, *et seq.*

130. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 111.

131. Defendant's acts violate, and plaintiff State of Idaho is entitled to relief under, the Idaho Competition Act, Idaho Code §§ 48-101 *et seq.*, and the Idaho Consumer Protection Act, Idaho Code §§ 48-601 *et seq*.

132. Plaintiff State of Illinois repeats and realleges each and every allegation contained in paragraphs 1 through 111.

133. Defendant's acts violate, and plaintiff State of Illinois is entitled to relief under the Illinois Antitrust Act, 740 ILCS 10/1 et seq., including without limitation 740 ILCS 10/3(3).

134. Plaintiff State of Kansas repeats and realleges each and every allegation contained in paragraphs 1 through 111.

135. Defendant's acts violate, and plaintiff State of Kansas is entitled to relief under, the laws of the State of Kansas, including, without limitation: the Kansas Restraint of Trade Act, Kansas Statutes Annotated 50-101 *et seq.* and its predecessor; the Kansas Consumer Protection Act, Kansas Statutes Annotated 50-101 *et seq.* and its predecessor; the common laws of Kansas including, without limitation: the common law of fraud, unconscionable acts or practices, deceptive acts and practices, unfair methods of competition, and unjust enrichment.

136. Plaintiff Commonwealth of Kentucky repeats and realleges each and every allegation contained in paragraphs 1 to111.

137 Defendant's acts violate, and plaintiff Commonwealth of Kentucky is entitled to relief under, the Kentucky Antitrust Law, KRS 367.175, the Kentucky Consumer Protection Act KRS 367.110 *et seq.*, and the common law of Kentucky.

138. Plaintiff State of Louisiana repeats and realleges each and every allegation contained in paragraphs 1 through 111.

139. Defendant's acts violate, and plaintiff State of Louisiana is entitled to relief under, the Louisiana Antitrust Act, La. R.S. 51: 121, *et seq.* and La. R.S. 51:1401, *et seq***.**

140. Plaintiff State of Maryland repeats and realleges each and every allegation contained in paragraphs 1 through 111.

141. Defendant's acts violate, and plaintiff State of Maryland is entitled to relief under, the Maryland Antitrust Act, Md. Com. Law Code Ann. § 11-201, *et seq.* (2000).

142. Plaintiff Commonwealth of Massachusetts repeats and realleges each and every allegation contained in paragraphs 1 through 111.

143. Defendant's acts violate, and plaintiff Commonwealth of Massachusetts is entitled to relief under, the Massachusetts Consumer Protection Act, G.L. c.93A s.2 et seq.

144. Plaintiff State of Michigan repeats and realleges each and every allegation contained in paragraphs 1 to 111.

145. Defendant's acts violate, and plaintiff State of Michigan is entitled to relief under, the Michigan Antitrust Reform Act, Mich. Comp. Laws Ann. § 445.776 *et seq*., the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901 *et seq.*, the common law of Michigan, and Mich. Comp. Laws Ann. § 14.28 and § 14.201.

146. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 111.

147. Defendant's acts violate, and plaintiff State of New York is entitled to relief under, New York General Business Law §§ 340-347, 349 and also constitute fraudulent or illegal acts under New York Exec. Law § 63(12).

148. Plaintiff State of North Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 111.

149. Defendant's acts violate, and plaintiff State of North Carolina is entitled to relief under, N.C. Gen. Stat. §§ 75-1, -1.1, 2.1 and the common law of North Carolina.

150. Plaintiff State of Ohio repeats and realleges each and every allegation contained in paragraphs 1 through 111.

151. Defendant's acts violate, and plaintiff State of Ohio is entitled to relief under, Ohio's Antitrust Law, Ohio Revised Code, §§ 109.81 and 1331.01 *et seq*. and the common law of Ohio.

152. Plaintiff State of Oklahoma repeats and realleges each and every allegation contained in paragraphs 1 through 111.

153. Defendant's act violate, and plaintiff State of Oklahoma is entitled to relief under, the Oklahoma Antitrust Reform Act, 79 O.S. § 201 *et seq.*, and the Oklahoma Consumer Protection Act, 15 O.S. § 751 *et seq*.

154. Plaintiff State of Oregon repeats and realleges each and every allegation contained in paragraphs 1 through 111.

155. Defendant's act violate, and plaintiff State of Oregon is entitled to relief under, the Oregon Antitrust Act, ORS 646.705, *et seq.*

156. Plaintiff Commonwealth of Pennsylvania repeats and realleges each and every allegation contained in paragraphs 1 through 111.

157. Defendant's acts violate, and plaintiff Commonwealth of Pennsylvania is entitled to relief under, Pennsylvania common law doctrines against monopolies, fraudulent misrepresentation and unjust enrichment and the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201 *et seq.*, and an action may be brought by the Attorney General and relief granted under 71 P.S. § 732-204 (c), 71 P.S. § 732-204 (d), 71 P.S. §§ 201-4, 201-4.1 and 201-8.

158. Plaintiff Commonwealth of Puerto Rico repeats and realleges each and every allegation contained in paragraphs 1 through 111.

159. Defendant's acts violate, and plaintiff Commonwealth of Puerto Rico is entitled to relief under, Act No. 77 of June 25, 1964, "Act to Prohibit Monopolistic Practice and Protect Fair and Free Competition in Trade and Commerce", 10 P.R. Laws Ann. §§ 257-276, and Act No. 118 of June 25, 1971, "Class Suit for Consumers of Goods and Services", 32 P.R. Laws Ann. §§ 3341-3344. The laws of the Commonwealth of Puerto Rico are included in the term "state law" as used in this complaint.

160. Plaintiff State of Rhode Island repeats and realleges each and every allegation contained in paragraphs 1 through 111.

161. Defendant's acts violate, and plaintiff State of Rhode Island is entitled to relief under, Rhode Island Code of Laws §§ 6-36 *et seq.*

162. Plaintiff State of South Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 111.

163. Defendant's acts violate, and plaintiff State of South Carolina is entitled to relief under, South Carolina Unfair Trade Practices Act, §§ 39-5-10 *et seq.*

164. Plaintiff State of Texas repeats and realleges each and every allegation contained in paragraphs 1 through 111.

165. Defendant's acts violate, and plaintiff State of Texas is entitled to relief under, Texas Business and Commerce Code § 15.01 *et seq.*

166. Plaintiff State of Utah repeats and realleges each and every allegation contained in paragraphs 1 through 111.

167. Defendant's acts violate, and plaintiff State of Utah is entitled to relief under, the Utah Antitrust Act, Utah Code Ann. Sec. 76-10-911 *et seq.* and the common law of Utah.

168. Plaintiff State of Vermont repeats and realleges each and every allegation contained in paragraphs 1 through 111.

169. Defendant's acts violate, and plaintiff State of Vermont is entitled to relief under, the Vermont Consumer Fraud Act, 9 Vermont Statutes Annotated, Chapter 63, and the common law of Vermont.

170. Plaintiff Territory of the United States Virgin Islands repeats and realleges each and every allegation contained in paragraphs 1 through 111.

171. Defendant's acts violate, and plaintiff Territory of the United States Virgin Islands is entitled to relief under, Territory of the United States Virgin Islands Code of Laws 11 V.I.C. §§1503 & 1507. *et seq.*

172. Plaintiff State of Washington repeats and realleges each and every allegation contained in paragraphs 1 through 111.

173. Defendant's acts violate, and plaintiff State of Washington is entitled to relief under, Wash. Rev. Code 19.86 RCW.

174. Plaintiff State of Wisconsin repeats and realleges each and every allegation contained in paragraphs 1 through 111.

175. Defendant's acts violate, and plaintiff State of Wisconsin is entitled to relief under, § 133.03 Wis. Stats. and § 133.16-18, Wis. Stats.

PRAYER FOR RELIEF

Accordingly, the Plaintiff States demand judgment as follows:

1. Adjudge and decree that Bristol engaged in conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

2. Adjudge and decree that Bristol engaged in conduct in violation of each of the state statutes and common law enumerated in this Complaint;

3. Enjoin and restrain, pursuant to federal and state law, Bristol, its affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with them, from engaging in any conduct and from adopting any practice, plan, program or device having a similar purpose or effect to the anticompetitive actions set forth above;

4. Award to Plaintiff States such other equitable relief, including, but not limited to, restitution and disgorgement, as the Court finds appropriate to redress Bristol's violations of state law;

5. Award to the Plaintiff States all damages sustained by and permitted to be recovered by the States, and all additional damages, penalties and other monetary relief provided by applicable law, including but not limited to treble damages;

6. Award to each Plaintiff State the maximum civil penalties allowed by law;

7. Award to each Plaintiff State its costs of this action, including reasonable attorneys' fees, and where applicable, expert fees; and,

8. Direct such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff States demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues triable of right by jury.

Dated: June _____, 2002

Respectfully submitted,

PLAINTIFF STATES:

STATE of OHIO
BETTY D. MONTGOMERY
Attorney General

_____

Alan Witten
Assistant Attorney General
Mitchell L. Gentile
Principal Attorney
Beth A. Finnerty
Senior Attorney
Antitrust Section
140 East Town Street, 12th Floor
Columbus, OH 43215
Phone: (614) 466-4328
Fax: (614) 995-0266

STATE of MARYLAND
CARMEN M. SHEPARD
Deputy Attorney General

_____
Meredyth Smith Andrus
Assistant Attorney General
Ellen S. Cooper
Chief, Antitrust Division
200 St. Paul Street
Baltimore, MD 21202
Phone: (410) 576-6470
Fax: (410) 576-7830

STATE of FLORIDA
ROBERT A. BUTTERWORTH
Attorney General
Richard E. Doran
Deputy Attorney General
Patricia A. Conners
Chief, Antitrust Section
Craig S. Farringer
Nicholas J Weilhammer
Assistant Attorneys General
PL-01, The Capitol
Tallahassee, FL 32399-1050
Phone: (850) 414-3600
Fax: (850) 488-9134

STATE of ALABAMA
BILL PRYOR
Attorney General
Jeff Long
Assistant Attorney General
Consumer Protection/Antitrust Division
11 South Union Street
Montgomery, AL 36130
Phone: (334) 242-7333
Fax: (334) 242-2433

STATE of ALASKA
BRUCE M. BOTELHO
Attorney General
Clyde E. Sniffen, Jr.
Assistant Attorney General
1031 W. 4th Avenue, Suite 200
Anchorage, AK 95501
Phone: (907) 269-5100

STATE of ARIZONA
JANET NAPOLITANO
Attorney General
Timothy A. Nelson
Special Counsel and Antitrust Unit Chief
David D. Weinzweig
Assistant Attorney General
1275 West Washington Street
Phoenix, AZ 85007
Phone: (602) 542-7752
Fax: (602) 542-9088

STATE of ARKANSAS
MARK PRYOR
Attorney General
Teresa Brown
Senior Assistant Attorney General
323 Center St., Ste. 200
Little Rock, AR 72201
Phone: (501) 682-3561

STATE of CALIFORNIA
BILL LOCKYER
Attorney General
Peter Siggins
Chief Deputy Attorney General
Richard M. Frank
Chief Assistant Attorney General
Kathleen E. Foote
Acting Senior Assistant Attorney General
Barbara Motz
Supervising Deputy Attorney General

Paula Lauren Gibson
Deputy Attorney General
300 South Spring Street,
12th Floor North Tower
Los Angeles, CA 90013
Phone: (213) 897-0014

STATE of CONNECTICUT
RICHARD BLUMENTHAL
Attorney General
Steven M. Rutstein
Department Head, Antitrust Department
Arnold B. Feigin
Assistant Attorney General
110 Sherman Street
Hartford, CT 06105
Phone: (860) 808-5540
Fax: (860) 808-5585

STATE of DELAWARE
M. JANE BRADY
Attorney General
Marsha Kramarck
Deputy Attorney General
Department of Justice, Antitrust Unit
820 N. French Street, 6th floor
Wilmington, DE 19801
Phone: (302) 577-5180
Fax: (302) 577-6630

DISTRICT of COLUMBIA
ROBERT R. RIGSBY
Corporation Counsel
Don Allen Resnikoff
Assistant Corporation Counsel
441 4th Street, N.W., Suite 450-N
Washington, D.C. 20001
Phone: (202) 727-6241
Fax: (202) 727-6546

STATE of IDAHO
ALAN G. LANCE
Attorney General
Brett T. DeLange
Deputy Attorney General
Consumer Protection Unit
Office of the Attorney General
Len B. Jordan Building
650 W. State St., Lower Level
P. O. Box 83720
Boise, ID 83720-0010
Phone: (208) 334-2424
Fax: (208) 334-2830

STATE of ILLINOIS
JAMES E. RYAN
Attorney General
Robert W. Pratt
Chief, Antitrust Bureau
100 West Randolph St., 13th Floor
Chicago, IL 60601
Phone: (312) 814-3722

STATE of KANSAS
CARLA J. STOVELL
Attorney General
Rex G. Beasley
Assistant Attorney General
Shelley King
Assistant Attorney General
120 SW 10th Avenue, 2nd Floor
Topeka, KS 66612-1597
Phone: (785) 296-3751
Fax: (785) 291-3699

COMMONWEALTH of KENTUCKY
ALBERT B. CHANDLER III
Attorney General
David R. Vandeventer
Assistant Attorney General
Consumer Protection Division
1024 Capital Center Dr.
Frankfort, KY 40601
Phone: (502) 696-5389

STATE of LOUISIANA
RICHARD P. IEYOUB
Attorney General
Jane Bishop Johnson
Assistant Attorney General
Louisiana Department of Justice
301 Main Street, Suite 1250
Baton Rouge, LA 70804
Phone: (225) 342-2754
Fax: (225) 342-9637

COMMONWEALTH of MASSACHUSETTS
THOMAS F. REILLY
Attorney General
Judith M. Whiting
Assistant Attorney General
Consumer Protection and Antitrust Division
One Ashburton Place
Boston, MA 02108
Phone: (617) 727-2200
Fax: (617) 727-5765

STATE of MICHIGAN
JENNIFER M. GRANHOLM
Attorney General
Paul F. Novak
Michelle M. Rick
Assistant Attorneys General
Consumer Protection Division
Antitrust Section
G. Mennen Williams Building, 6th Floor
525 W. Ottawa Street
Lansing, MI 48913
Phone: (517) 241-2060
Fax: (517) 335-1935

STATE of NEW YORK
ELIOT SPITZER
Attorney General
Jay Himes (JH 7714)
Chief, Antitrust Bureau
Richard L. Schwartz (RS 7913)

John A. Ioannou (JI 8338)
Assistant Attorneys General
Antitrust Bureau
120 Broadway, Suite 26-01
New York, NY 10271
Phone: (212) 416-8284, (212) 416-8268
Fax:(212) 416-6015, (212) 416-8475

STATE of NORTH CAROLINA
ROY A. COOPER, III
Attorney General
K.D. Sturgis
North Carolina Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629
Phone: (919) 716-6000
Fax: (919) 716-6050

STATE of OKLAHOMA
W.A. DREW EDMONDSON
Attorney General
Thomas A. Bates
Assistant Attorney General
4545 N. Lincoln Boulevard, Suite 260
Oklahoma City, OK 73105
Phone: (405) 521-4274
Fax: (405) 528-1867

STATE of OREGON
HARDY MYERS
Attorney General
Andrew E. Aubertine
Assistant Attorney General
Michelle Teed
Assistant Attorney General
Oregon Department of Justice
1162 Court Street, NE
Salem, OR 97310
Phone: (503) 378-4732
Phone: (503) 229-5725
Fax: (503) 378-5187

COMMONWEALTH of PENNSYLVANIA
D. MICHAEL FISHER
Attorney General
James A. Donahue III
Chief Deputy Attorney General
Andrea J. Myers
Tracy W. Wertz
Deputy Attorneys General
Antitrust Section
14th Floor, Strawberry Square
Harrisburg, PA 17120
Phone (717) 787-4530
Fax: (717) 705-7110

COMMONWEALTH of PUERTO RICO
ANABELLE RODRIGUEZ
Secretary of Justice
Irma Rodriguez-Justiniano
Deputy Attorney General
Office of Monopolistic Affairs
PO Box 9020192
San Juan, PR 00902-0192
Phone: (787) 723-9583
Fax: (787) 725-2475

STATE of RHODE ISLAND
SHELDON WHITEHOUSE
Attorney General
J.O. Alston
Special Assistant Attorney General
150 South Main Street
Providence, RI 02903
Phone: (401) 274-4400
Fax: (401) 274-3050

STATE of SOUTH CAROLINA
CHARLES M. CONDON
Attorney General
C. Havird Jones, Jr.
Senior Assistant Attorney General
Rembert C. Dennis Building

1000 Assembly Street, Suite 501
Columbia, SC 29211-1549
Phone: (803) 734-3654
Fax: (803) 734-3677

STATE of TEXAS
JOHN CORNYN
Attorney General
Howard G. Baldwin, Jr.
First Assistant Attorney General
Jeffrey S. Boyd
Deputy Attorney General for Litigation
Paul D. Carmona
Chief, Consumer Protection Division
Mark Tobey
Assistant Attorney General
Chief, Antitrust Section
William J. Shieber
Assistant Attorney General
P. O. Box 12548
Austin, Texas 78711-2548
Phone: (512) 463-2185
Fax: (512) 320-0975

STATE of UTAH
MARK L. SHURTLEFF
Attorney General
Wayne Klein
Assistant Attorney General
160 East 300 South, 5th Floor
P.O. Box 140872
Salt Lake City, UT 84114-0872
Phone: (801) 366-0358

STATE of VERMONT
WILLIAM H. SORRELL
Attorney General
David Borsykowsky
Assistant Attorney General
Julie Brill
Assistant Attorney General and

Director of Antitrust Unit
109 State Street
Montpelier, VT 05609-1001
Phone: (802) 828-1057
Fax: (802) 828-5341

TERRITORY of The UNITED STATES VIRGIN ISLANDS
IVER A. STRIDIRON
Attorney General
48B-50C Kronprindsens Gade
GERS Building, 2nd Floor
St. Thomas, U.S. VI 00802
Phone: (340) 714-9610
Fax: (340) 774-9710

STATE of WASHINGTON
CHRISTINE O. GREGOIRE
Attorney General
Donivan R. Irby
Assistant Attorney General
Tina E. Kondo
Senior Assistant Attorney General
Chief, Antitrust Division
900 Fourth Avenue, Suite 2000
Seattle, WA 98164
Phone: 206-464-7589

STATE of WISCONSIN
JAMES E. DOYLE
Attorney General
Kevin J. O'Connor
Assistant Attorney General
Office of the Attorney General
17 West Main Street
Madison, WI 53702
Phone: (608) 266-8986
Fax: (608) 267-2778